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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,960

07/08/2005

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01/07/2009

EXAMINER

PATEL, PRITESH ASHOK

ART UNIT

PAPER NUMBER

3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,960	<b>Applicant(s)</b> FUKAI ET AL.	
	<b>Examiner</b> PRITESH PATEL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/08/2005, 08/31/2007, 08/21/2008, and 12/17/2008</u> .      | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 5, and 7-9 are rejected under 35 U.S.C. 102 (e) as being anticipated by Hishikawa (US 6808161 B1).

Concerning claim 1, Hishikawa discloses a sealing valve for a medical apparatus made of an elastic material and having a valve hole at a center which is opened without penetration by a male connection port of said medical apparatus (Fig 1, 3, 4, 5, and 6, elements 32, 33, 34, and 4).

Concerning claim 5, Hishikawa discloses a cylindrical shaped sealing valve with an arched convex face (Fig 8a and element 3 and 31b).

Concerning claim 7, Hishikawa discloses a connection port (2), a sealing valve as discussed above, a sleeve portion 21 pressing the sealing valve to create a hermetically sealed junction, a screw piece (218) on upper portion of said sleeve in which a syringe can lock in (Fig 12).

Concerning claim 8, Hishikawa discloses an upper end of a sealing valve (3) that is substantially coincident with a sleeve portion (21) and a cushion portion (lower part of element 3) that depresses when a male connection port is inserted into said sleeve

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portion; the depression stops at a predetermined position (Fig 12).

Concerning claim 9, Hishikawa discloses a sleeve portion that serves as a cap to a sealing valve and on said sleeve portion are vertical ridges and valleys (218) that can lock a syringe and said cap together without rotation them against one another (Fig 12).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hishikawa.

Concerning claim 4, Hishikawa discloses a sealing valve as disclosed above. It would have been obvious to one of ordinary skill in the art at the time of the invention that a cylindrical base as seen in Fig 1 does not have to be cylindrical in order to provide a sealing function; it could in turn be semi-spherical as that shape would provide adequate transverse force to hermetically seal said sealing valve.

Concerning claim 6, Hishikawa discloses a sealing valve with a raised surface portion (Fig 1 and element 30). It would have been obvious to one of ordinary skill in art at the time of the invention to see that the raised portion is an interface for the male connection part of a medical apparatus and it would be obvious to define the area further and create a ring portion.

7. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hishikawa in view of Schneider (US 5836967).

Concerning claims 11 and 12, Hishikawa discloses a sealing valve, a connection port, a cap member having a sleeve portion, protruding stria on said sleeve portion, a resistance application portion where a locking syringe ceases to couple further, and upon which further insertion deforms said sealing valve, all as disclosed above.

Hishikawa further discloses a mixed injection tube having multiple connection ports (Fig 19). It would have been obvious to one of ordinary skill that as the screw portion on the

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upper end of the cap member stops a syringe cannot go further if it has a counter-part to the screw portion and that a double threaded portion would also stop further screwing in of a locking syringe. It would have been further obvious to one of ordinary skill in the art at the time of the invention that the screw portions on the sleeve portion could be male or female and said medical apparatus, specifically a syringe, may have a counter-part to fit said screw portion accordingly. Hishikawa fails to disclose connection ports at both ends of an infusion tube. Schneider discloses many connection ports connecting to an infusion tube (Fig 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hishikawa with multiple connection ports along an infusion tube as taught by Schneider to have multiple points of connection for any medical apparatus needed.

8. Concerning claims 13, 14, and 15, in addition to the above disclosure, Schneider discloses multiple infusion lumens (Fig 1). It would have been obvious to one of ordinary skill to modify Hishikawa with a multiple lumen catheter as taught by Schneider to be able to implement a connection port as disclosed above in each branch connection tube (elements 23, 24, 12, and 13 of Schneider Fig 1). It would further have been obvious that each branch connection tube can connect with a syringe and that each branch connection tube can lead to any lumen in said catheter.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-

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7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./  
Examiner, Art Unit 3763  
1/02/2009

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763